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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,462	11/22/2000	Adnan Shennib	022176-001522US	3046

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EXAMINER

FAULK, DEVONA E

ART UNIT	PAPER NUMBER
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2644

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,462

Applicant(s)

SHENNIB, ADNAN

Examiner

Devona E. Faulk

Art Unit

2644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 4/13/2005, with respect to the rejection(s) of amended claim(s) 1,25 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Finlayson and Steer

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 13,15,16-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Haertl (U.S. Patent 4,987,597).

Regarding **claim 13**, Haertl discloses a hearing system (Figure 1) fabricated and adapted to be positioned entirely in the ear canal for extended wear (column 3) , comprising:

a hearing device (Figure 1) assembled and dimensioned to be medially positioned in the ear canal and

an intracanal shield (12; Figure 1; column 3, lines 20-33) shaped and dimensioned to be laterally positioned with respect to said hearing device, so that said intracanal shield caps the cavity of said ear canal, said intracanal shield comprising:

a conforming perimeter for fitting in a retaining manner along the cross sectional wall (column 4, lines 26-30) of the ear canal and

a central porous member (14, Figures 4-15) for air ventilation with respect to said hearing device, and having pores sized to prevent penetration of fluids and solids there through (column 3, lines 10-20).

All elements of **claim 15**, are comprehended by the rejection of claim 13 (column 3, lines 8-10).

All elements of **claims 16-18** are comprehended by the rejection of claim 13 (column 2, line 1; column 3, lines 10-20).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1,3,4-6 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Finlayson (U.S. Patent 6,145,226).

Regarding **claims 1 and 25**, Haertl discloses an intracanal shield (12, Figure 1; column 3, lines 7-34) for positioning entirely in the ear canal and capping the cavity of said ear canal, comprising:

a conforming perimeter adapted to fit in a retaining manner along the cross sectional wall of the ear canal cavity (cap, column 3, lines 5-25; reads on an acoustically permeative cap of claim 25) ;

a central porous member (14, Figures 4-15) having pores sized for allowing air to pass through said porous member while preventing passage of fluids and solids therethrough (column 3, lines 10-25),

said intracanal shield (Figures 4-11; column 3, lines 20-33; column 4, lines 1-25), when fitted in said retaining manner in the ear canal cavity, being positioned laterally with respect to a miniature hearing device medially positioned in close proximity to the eardrum, whereby to protect said hearing device against penetration of fluids and debris through said porous member while allowing air-borne sounds to reach said hearing device (column 3, lines 10-20).

Haertl teaches that the porous member is air permeable (column 3, line 32; reads on providing a circulated air flow of claims 1 and 25) but fails to disclose that this helps reduce infection .

Haertl fails to disclose but Finlayson teaches that air circulation can prevent infection (column 5, lines 24-25)(reads on air circulation sufficient to reduce an incidence of infection of claims 1 and 25). It would have been obvious to modify Haertl such that the air circulation will reduce infection as taught by Finlayson in order to reduce the probably of infection to the wearer of the device.

Regarding **claim 3**, Haertl as modified by Finlayson disclose wherein said intracanal shield is attached to said canal hearing device for insertion into and removal from said ear canal along with hearing device ((column 3, lines 8-10).

Regarding **claims 4-6**, Haertl as modified by Finlayson disclose wherein said porous member is hydrophobic, oleophobic and comprises a porous membrane ((column 2, line 1; column 3, lines 10-20).

6. **Claim 2,7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Finlayson (U.S. Patent 6,145,226) in further view of Flagler (U.S. Patent 6,134,333).

Regarding **claim 2**, Haertl as modified by Finlayson fails to disclose but Flagler wherein said intracanal shield is separate from said canal hearing device for independent insertion and removal while said hearing device is positioned in-situ. Flagler discloses a cerumen barrier (10) including a sound passage endcap (12) having a disposable oleophobic and hydrophobic barrier and fastened by a retainer ring (14) , the sound passage endcap (12) being removable from the retainer ring and disposable when the wax build-up becomes too great (column 3, lines 21-49). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Flagler's concept of independent insertion as claimed for the benefit of having a shield that is more easily replaced.

Regarding **claim 7**, Haertl as modified by Finlayson fails to disclose but Flagler teaches wherein said intracanal shield is composed of disposable material for cost-effective single use of said shield. Flagler discloses a cerumen barrier (10) including a

Art Unit: 2644

sound passage endcap (12) having a disposable oleophobic and hydrophobic barrier and fastened by a retainer ring (14), the sound passage endcap (12) being removable from the retainer ring and disposable when the wax build-up becomes too great (column 3, lines 21-49). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Flagler's concept of a disposable shield for the benefit of having a cerumen barrier that is more easily replaced.

7. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Finlayson (U.S. Patent 6,145,226) in further view of Steer (U.S. Patent 5,352,316).

Regarding **claim 10**, Haertl as modified by Finlayson fails to disclose but Steer teaches of wherein pores are sized in the range of 1 to 10 microns (abstract). It would have been obvious to modify Haertl as modified by Finlayson by having the pores sized between 1 and 10 microns as taught by Anderson in order to have a high porous membrane that is liquid-impermeable(abstract).

8. **Claims 8,9,11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Finlayson (U.S. Patent 6,145,226) in further view of Brown et al. (U.S. Patent 6,129,174).

Regarding **claim 8**, Haertl as modified by Finlayson fails to disclose but Brown teaches of wherein said shield is at least partially composed of polyurethane foam. Brown teaches on a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7,

lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of polyurethane foam for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

Regarding **claim 9**, Haertl as modified by Finlayson fails to disclose but Brown teaches wherein said shield is at least partially composed of silicone material. Brown teaches on a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of silicone for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

Regarding **claim 11**, Haertl as modified by Finlayson fails to disclose but Brown teaches wherein said intracanal shield is shaped and dimensioned to be positioned deep in the ear canal past the hair and cerumen production area therein. Brown discloses a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), adapted for use with an intracanal receiver module can be deeply inserted into the ear canal of the user while making minimal contact with the walls of the ear canal (See Abstract). Therefore, the concept of having a intracanal device that can be deeply inserted in the ear canal was well known at the time of filing. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Brown's

Art Unit: 2644

concept of deeply inserting an intracanal shield so that it could be inserted deeply into the ear for the benefit of enabling a deeper insertion of the hearing aid.

9. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Finlayson (U.S. Patent 6,145,226) in further view of Oliveira (U.S. Patent 5,401,920).

Regarding **claim 12**, Haertl as modified by Finlayson fails to disclose but Oliveira teaches wherein said intracanal shield has an oval cross-sectional shape adapted to fit comfortably in a cross section of the ear canal. Oliveira discloses the concept of an intracanal shield having an oval cross-sectional shape (Figure 1). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Oliveira's concept of an intracanal shield having an oval cross-sectional shape in order to better conform better to a device.

10. **Claim 14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Flagler (U.S. Patent 6,134,333).

Regarding **claim 14**, Haertl fails to disclose but Flagler teaches wherein said intracanal shield is separate from said hearing device for independent insertion into and removal from the ear while said hearing device is positioned in-situ. Flagler discloses a cerumen barrier (10) including a sound passage endcap (12) having a disposable oleophobic and hydrophobic barrier and fastened by a retainer ring (14), the sound passage endcap (12) being removable from the retainer ring and disposable when the wax build-up becomes too great (column 3, lines 21-49). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Haertl so

Art Unit: 2644

that the cap was capable of being inserted as claimed for the benefit of having a cap that is more easily replaced.

11. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Flagler (U.S. Patent 6,134,333) in further view of Leedom (U.S. Patent 5,825,896).

Regarding **claim 19**, Haertl fails to disclose but Leedom teaches wherein said intracanal shield is disposable. Flagler discloses a cerumen barrier (10) including a sound passage endcap (12) having a disposable oleophobic and hydrophobic barrier and fastened by a retainer ring (14), the sound passage endcap (12) being removable from the retainer ring and disposable when the wax build-up becomes too great (column 3, lines 21-49). It would have been obvious to modify Haertl by making the cap disposable in order to be able to discard after use.

Haertl as modified by Flagler fails to disclose but Leedom teaches of a disposable hearing aid (column 1, lines 26-27).

It would have been obvious to modify Haertl as modified by Flagler by making the hearing aid a disposable one so as to reduce the cost of a hearing aid (column 1, lines 26-27)

12. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Steer (U.S. Patent 5,352,316).

Regarding **claim 22**, Haertl fails to disclose but Steer teaches of wherein pores are sized in the range of 1 to 10 microns (abstract). It would have been obvious to modify Haertl as modified by Finlayson by having the pores sized between 1 and 10

Art Unit: 2644

microns as taught by Anderson in order to have a high porous membrane that is liquid-impermeable(abstract).

13. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Oliveira (U.S. Patent 5,401,920).

Regarding **claim 24**, Haertl as modified by Finlayson fails to disclose but Oliveira teaches wherein said intracanal shield has an oval cross-sectional shape adapted to fit comfortably in a cross section of the ear canal. Oliveira discloses the concept of an intracanal shield having an oval cross-sectional shape (Figure 1). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Oliveira's concept of an intracanal shield having an oval cross-sectional shape in order to better conform better to a device.

14. **Claims 20,21,23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Haertl (U.S. Patent 4,987,597) in view of Brown et al. (U.S Patent 6,129,174).

Regarding **claim 20**, Haertl fails to disclose but Brown teaches of wherein said intracanal shield is at least partially composed of polyurethane foam. Brown teaches on a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of polyurethane foam for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

Regarding **claim 21**, Haertl fails to disclose but Brown teaches wherein said intracanal shield is at least partially composed of silicone material. Brown teaches on a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), made of a compressible material, such as polyurethane foam or silicone, to conform to the shape of ear canal, thus sealing the ear canal (column 7, lines 7-15). Thus it would have been obvious to one of ordinary skill in the art to have the shield at least partially composed of silicone for the benefit of enabling the intracanal device to better conform to the shape of ear canal, thus sealing the ear canal.

Regarding **claim 23**, Haertl fails to disclose but Brown teaches wherein said shearing system is fabricated and dimensioned to be positioned deep in the ear canal past the hair and cerumen production area therein. Brown discloses a replaceable acoustic coupler, including a cerumen-protecting feature (Abstract), adapted for use with an intracanal receiver module can be deeply inserted into the ear canal of the user while making minimal contact with the walls of the ear canal (See Abstract). Therefore, the concept of having a intracanal device that can be deeply inserted in the ear canal was well known at the time of filing. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use Brown's concept of deeply inserting an intracanal shield so that it could be inserted deeply into the ear for the benefit of enabling a deeper insertion of the hearing aid.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devona E. Faulk whose telephone number is 571-272-7515. The examiner can normally be reached on 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vivian Chin can be reached on 571-272-7848. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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